



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/110,720	07/07/98	BILLING-MEDEL	P 6130.US.P1

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HM12/1213

EXAMINER

ZITOMER, S

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 12/13/99

**Pleas find below and/or attached an Office communication concerning this application r  
pr ceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/110,720

Applicant(s)

BILLING-MEDEL et al.

Examiner  
Stephanie Zitomer

Group Art Unit  
1655



☒ Responsive to communication(s) filed on Oct 5, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-32 and 34-48 is/are pending in the application.

Of the above, claim(s) 1-10, 15-32, 34-37, and 40-44 is/are withdrawn from consideration.

☒ Claim(s) 38 is/are allowed.

☒ Claim(s) 11-14, 39, and 45-48 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### Prosecution status

1. Receipt of the amendment filed October 5, 1999 is acknowledged.
2. All objections and rejections set forth in the previous Office action, paper no. 8, mailed May 25, 21999, are withdrawn in view of the amendments to the specification and claims. Applicant's comments have been fully considered.

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

### Rejection under 35 USC 112, second paragraph: Indefiniteness

3. Claims 11-14, 39 and 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims fail to define the metes and bounds of the claimed invention because "specifically binds to" is a recited property of the polynucleotide but it is not defined in the claims or in the specification. "Specifically" is a relative term carrying an exclusionary connotation. While the specification provides discussion and examples of "specific" binding it does not define the term as a property of a polynucleotide nor does it point out what materials may be excluded. Therefore, the skilled practitioner in the art would not have been apprised of the scope of the claimed invention polynucleotide. Applicant's discussion in support of the new phrase, "specifically binds to", has been fully considered but it has not been found persuasive. The cited portions of the specification provide discussion and examples as previously stated but do not define the scope of "specifically binds to". It is suggested to replace "specifically binds to" with "hybridizes to" and to claim the polynucleotide in terms of its function, i.e., probe and/or primer, which provides a generic description of its size and "binding" property.

### Rejection under 35 USC 102(b)/103(a): Anticipation and/or obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

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was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11-14 and 45-48 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Strausberg (Accession No. AA639700, EST database, 1993) for SEQ ID NO:2; Hillier et al. (Accession No. AA256868, EST database, 1996) and Strausberg (Accession No. AA639700, EST database, 1993) for SEQ ID NO:3; Strausberg (Accession No. AA228353 and AA228426, EST database, 1996) and Hillier et al. (Accession NO. H05698, EST database, 1995) for SEQ ID NO:6; Matsubara et al. (AC T25603 (Geneseq) WO 95/14772) for SEQ ID NOS: 9, 15 and 16; Hillier et al., (Accession No. W79647, EST database, 1992) for SEQ ID NO:11. Each of the references discloses a polynucleotide sequence that "specifically binds", interpreted as "hybridizes", to a polynucleotide of claim 11 identified by its SEQ ID NO: as shown in the sequence search printouts. The rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because the references are silent with regard to the embodiments of claims 12-14 and 45-48, viz., how the polynucleotide was made, that it encodes a BS200 epitope and that it comprises a sequence of at least about 10, 12, 15 or 20 nucleotides. However, these properties are deemed to be inherent in the reference polynucleotides because the reference polynucleotides meet the limitation of "comprising a polynucleotide sequence that [hybridizes] to" one or more of the sequences recited in claim 11. The burden is on applicant to show that the claimed polynucleotide is either different or nonobvious over that of references.

5. Claim 39 is rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsubara et al. (AC T25603 (Geneseq) WO 95/14772). The reference discloses a polynucleotide sequence that "specifically

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binds", interpreted as "hybridizes", to a polynucleotide of claim 39 identified by its SEQ ID NO: (15 or 16) as shown in the sequence search printouts. The rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Matsubara et al. is silent with regard to the property of being an "isolated gene". However, this property is deemed to be inherent in the reference polynucleotide because the reference polynucleotide meets the limitation of "comprising DNA that [hybridizes] to a polynucleotide having the sequence of SEQ ID NO:15, SEQ ID NO:16 or complements thereof" wherein the recited "isolated gene" has no defining characteristics of a gene such as encoding an amino acid sequence. The burden is on applicant to show that the claimed polynucleotide is either different or nonobvious over that of references.

#### Conclusion

6. This application contains claims 1-10, 15-32, 34-37 and 40-44 drawn to an invention nonelected with traverse in Paper No. 6, filed March 5, 1999. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

7. **Claim 38 is allowed.** Claims 11-14, 39 and 45-48 are rejected. However, SEQ ID NOS:1-3, 9, 14-16 and 31 are free of the prior art. SEQ ID NO:6 would be allowable if claimed in closed language, i.e., "consisting of". SEQ ID NO:11 has a single mismatch at nucleotide 62 with the EST of Hillier et al. (1992). It is unclear whether this difference is significant and therefore SEQ ID NO:11 also should be claimed in closed language.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

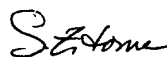
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In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephanie W. Zitomer, Ph.D.  
December 10, 1999

STEPHANIE W. ZITOMER  
PATENT EXAMINER